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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,624	01/26/2000	Carlos Picomell Darder	4948-2P/C/RCE	8816

7590 03/10/2004
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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/491,624

Applicant(s)

DARDER, CARLOS PICORNELL

Examiner

Sharmila S. Gollamudi

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-13, 15-40.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

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Applicant argues that although US patent 6,132,771, hereafter referred to as Depui et al, recognizes the need for an enteric coating to protect the proton pump inhibitor from the acidic gastric juices, Depui main objective does not provide for an enteric coating of the proton pump inhibitor.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner is unclear as to what exactly is being argued by the applicant since the applicant clearly states that Depui et al recognizes the need for an enteric coat to protect the acid susceptible proton inhibitor. It is quite clear that Depui et al disclose the use of an enteric coat as clearly seen on column 3, lines 18-23 wherein Depui states that Figure 1 is a cross-section of a dosage form comprising an acid susceptible proton pump inhibitor *in the form of an enteric coating layered pellet*.

Applicant argues that Depui et al fail to describe a stable and useful oral form of a proton pump inhibitor without an alkaline substance and at least one separating layer. It is argued that Depui fails to enable such a dosage form. Applicant claims that Depui et al never exemplify an embodiment without a separating layer.

Applicant's arguments have been fully considered but they are not persuasive. The Webster Dictionary defines *optional* as: involving an option: not compulsory. Further, option is defined as: 1) something that may be chosen 2) an item that is offered in addition to or in place of the standard. Thus, as noted by the applicant himself, the separating layer and alkaline substance are optional embodiments. The word "optional" in itself clearly denotes that if one were to exclude the *optional* separating layer and *optional* alkaline substance, it would not be detrimental to the dosage form. In regards

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to applicant's argument that if the separating layer and alkaline substance are excluded, then Depui et al would not be stable and enabled. Again, it is pointed out that if the separating layer and alkaline substance were absolutely critical to Depui's invention, then Depui would not insert the word optional. Additionally, column 10, lines 29-220 is pointed out wherein Depui states, "the optionally applied separating layer(s) is not essential for the invention." Lastly, page 13 of instant specification should be noted since it states that the instant dosage form can include alkaline substances, just as Depui et al state the optional use of an alkaline substance.

In regards to the argument that Depui does not exemplify the instant invention, the examiner points out that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiment. See *In re Susi*.

In regards to the "consisting essentially of" language, the examiner points out that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. The instant claim language does not exclude Depui's additional layers since they not detrimental to the dosage form and as discussed above are optional.

Applicant argues the merits of US patent 4,786,505, hereafter referred to as Lovgren et al. Appellant argues that Lovgren et al require a separating layer and alkaline substance; thus a skilled artisan would not be motivated to make a dosage form without the separating layer and alkaline substance.

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Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner relies upon Lovgren *solely* for the purpose of demonstrating the state of the art wherein a formulation containing only a single active, i.e. a proton pump inhibitor, is known in the art. The examiner does not rely on Lovgren's dosage formulation *per se*. Depui et al is utilized as the primary reference and discloses and suggests the broad aspect of the instant invention.

For argument sake, even if the secondary reference were removed, the examiner points out that Depui et al would still read over the prior art. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Therefore, the limitation of claim 35 is not a novel concept. It is acknowledged that Depui teaches the advantages of combination therapy (proton pump inhibitors and prokinetic agents); however "a known or obvious composition does not become patentable simply because it is described as somewhat inferior" See *In re Gurley*. Further, the examiner points to column 2, lines 25-31 wherein the reference states that "combination therapy is considered for patients whose predominant symptom is regurgitation...those with respiratory problems...those with cough and hoarseness related to reflux disease." Therefore, it is quite clear to a skilled artisan that if a patient did not experience the above symptoms as discussed by Depui, one would utilize a single active. The combination therapy discussed by Depui is an alternative embodiment.

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Applicant argues a side-by-side comparison of Depui et al and Lovgren et al. It is argued that the results demonstrate that without a separating layer, a stable dosage form is not yielded.

Applicant's arguments have been fully considered but they are not persuasive. As discussed previously, Lovgren's formulation is not relied upon to make the rejection of instant invention's formulation. Further, as discussed above, the instant invention is rejected over Depui et al alone without Lovgren et al's teachings. Therefore, the discussion of comparing Depui and Lovgren is rendered moot.

Applicant argues that the claimed invention as a whole is more stable since the enteric coating is stable because the active layer is homogenous and non-porous. Applicant argues that the instant invention utilizes a Wurster type bed coater, which distinguishes it from the prior art. It is argued applicant utilizes effective parameters to accomplish

The examiner points out that the applicant is relying on an argument of degree; i.e. the degree of stability of the instant invention compared to the prior art. However, these features are not recited or defined by the claims to distinguish it over the prior art.

In regards to the Wurster-type fluidized bed coater, firstly it is noted that only the process claims recite this limitation and not the product claims. Therefore, the distinguishable features argued by the applicant in regards to the product are moot. Further, the examiner points out that the applicant has not provided evidence only arguments demonstrating that a different and patentably distinguishable product is produced. Page 9 of instant specification is pointed out wherein applicant states that

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the: "Wurster" type fluid bed or the like in which the coating process is carried out minimizes the abrasion caused by roto granulation. From this statement, it can be ascertained that the claimed bed coater only minimizes abrasion and does not provide for any distinct features. Further, applicant argues that the Depui et al's process requires multi-step process and the instant invention does not require this; however it is pointed out that the process claims recite open claim language that does not exclude Depui's steps.

In regards to the use of "effective parameters" utilized in the instant invention, the examiner points out that it is obvious to one of ordinary skill in the art to manipulate the conditions set forth by the prior art to obtain the best possible results. Therefore, finding effective parameters is a routine process practiced by one of ordinary skill in the art. Further, applicant does not recite these effective parameters in the claims to enable one skilled in the art to product the same "superior product".

Therefore, the rejections are maintained and the claims are not distinguishable over the prior art.

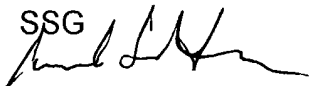
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG



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